REMARKS

Objections to the Specification:

Applicants have amended the specification as suggested by the Examiner.

Objections to the Claims:

Claims 1, 29 and 30 have been objected to for informalities. Applicants have amended the claims as recommended by the Examiner.

Rejection of the Claims under 35 USC § 112:

Claims 1, 5-17, and 20-28 have been has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants have amended the claim to remove the indefiniteness. Support for attachment of a T7 ligand to a component of a complex can be found in the specification on page 3 lines 17- 29, page 4 lines 13-18, page 12 lines 16-18.

Claims 1, 5-11, 29, and 30 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The action states that the disclosure describes a T7 p17 polypeptide ligand covalently attached to interferon α2b. Interferon is a drug (page 11 lines 27-34). Applicants have also shown covalent attachment of a T7 p17 ligand to streptavidin and biotin, components which can be incorporated into complexes, including liposome complexes and polymer complexes. Applicants have also observed delivery of a polyanion (dextran) to hepatocytes through both indirect streptavidin-biotin coupling and direct covalent linkage of a T7 p17 ligand to the polyanion (page 31 line 20 to page 32 line 34, see especially page 32 lines 33-34). As noted by the Examiner, Applicants have shown hepatocyte delivery of polynucleotides through non-covalent streptavidin-biotin linkage to T7 p17 ligands. Since the invention as been shown to work with small molecules, proteins, complexes and polyanions using both non-covalent and covalent linkages, there is no basis to expect that non-covalent linkage, but not covalent linkage, will be effective in delivering polynucleotides, which are themselves polyanions, to hepatocytes.

Claims 1, 5-11, 13, 16, 17, 20, 21, 22, and 27-30 have been rejected under 35 U.S.C. 112, first paragraph, for lack of enablement for a composition comprising any T7 ligand with any drug, complex and polynucleotide. The Action indicates that claims 12 and 22-25 are

enabled. Applicants have amended the claims to obviate the rejection. Specifically, Applicants have incorporated into claims 1, 29 and 30, the limitations of claims 12 and 22-25. In addition, Applicants have incorporated into claims 1, 29 and 30 additional T7 p17 ligands taken from the table on page 10 of the specification and on page 10 line 1 through page 11 line 5 of the specification.

Rejection of the Claims under 35 USC § 102:

Claim 1 has been rejected under 35 U.S.C. 102(b) as being anticipated by Studier et al. Examiner points to the teaching in Studier of a fusion protein comprising the first 11 amino acids of T7 gene 10 protein. However, Applicants have defined a T7 ligand as the hepatocyte targeting determinant that is present on T7 phage, the T7 phage p17 protein, and fragments of the T7 p17 protein. Gene 10 protein is not gene 17 protein (p17). Applicants request reconsideration of this 102 rejection.

Rejection of the Claims under 35 USC § 102/103:

Claims 1 and 3 have been rejected under 35 U.S.C. 102(e) or 103(a) as being anticipated by/obvious over Sim et al in view of Lutz-Freyermuth et al. Applicants have defined a T7 ligand as the hepatocyte targeting determinant that is present on T7 phage, the T7 phage p17 protein, and fragments of the T7 p17 protein. Gene 10 protein is not gene 17 protein (p17). Applicants request reconsideration of this 102/103 rejection.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1, 3, 5-11, 13-17, 20, 21, and 27-30 should be allowable.

Respectfully submitted,

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I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as express mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: Oct. 10, 2005

Kirk Ekena